In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 20-806V UNPUBLISHED

RONALD ORION,

Petitioner.

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: January 11, 2022

Special Processing Unit (SPU); Findings of Fact; Onset; Tetanus Diphtheria acellular Pertussis (Tdap) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA); Brachial Neuritis

David John Carney, Green & Schafle, LLC, Philadelphia, PA, for Petitioner.

Claudia Barnes Gangi, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CASE¹

On July 1, 2020, Ronald Orion filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that a Tdap vaccine Petitioner received on September 6, 2017, caused him to suffer the Table injury of Parsonage-Turner Syndrome (also known as brachial neuritis); alternatively that his brachial neuritis was caused-in-fact by his vaccination; or that he suffered a different Table Injury, shoulder injury related to vaccine

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

administration ("SIRVA"). Amended Petition filed October 22, 2020. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

I. Relevant Procedural History – Order to Show Cause

On November 19, 2020, Respondent filed his counsel's informal assessment of this case, pursuant to my Order, identifying a legal issue regarding the onset of Petitioner's alleged brachial neuritis. ECF No. 14 at 2. On July 14, 2021, I issued an Order to Show Cause, as it appeared based upon my review that Petitioner would neither be able to establish *any* form of Table claim - brachial neuritis or SIRVA. ECF No. 18. I therefore advised Petitioner that I would likely reassign this case from SPU, since all that remains to be litigated is some form of causation-in-fact claim that is not appropriate for resolution in SPU. ECF No. 18 at 2. I further advised that if I determined that Petitioner's Table claims must be dismissed, I would issue Findings of Fact and Conclusion of Law Dismissing Petitioner's Table Claims, and transfer the matter out of SPU. *Id.* at 3.

On August 17, 2021, Petitioner filed a Status Report in response to my Order to Show Cause, indicating that he "will consent to the Table claims of SIRVA and brachial neuritis being dismissed while preserving Petitioner's right to proceed under a causation-in-fact claim for either SIRVA and/or brachial neuritis after receipt of vaccination." ECF No. 19.

On September 14, 2018, Respondent filed a response to Petitioner's Show Cause Filing/Status Report, representing that he "does not object to (1) the transfer of this case out of the SPU, (2) the dismissal of the Table claims of SIRVA and brachial neuritis, or (3) [P]etitioner's request to preserve his right to proceed under a theory of causation-infact for his alleged brachial neuritis." ECF No. 20 at 1 (emphasis in original). Respondent, however, argues that "because 'SIRVA' is an injury defined by administrative rulemaking, . . . [P]etitioner may not pursue a cause-in-fact SIRVA claim." *Id.* Rather, Respondent asserts, Petitioner may only pursue a cause-in-fact claim to a specific shoulder injury if one can be established. *Id.* at 1-2.

II. Analysis and Findings of Fact

To establish a Table claim for brachial neuritis, onset of the injury must occur not less than two days, or more than 28 days, following vaccination. 42 C.F.R. § 100.3(a)(I)(B). However, in this case the record supports the conclusion that onset of Petitioner's symptoms occurred six hours³ after his receipt of the Tdap vaccine - thus

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³ Petitioner was seen at the emergency room of Orange Regional Medical Center on September 8, 2017, and reported the onset of his shoulder pain as follows:

precluding a Table claim for brachial neuritis. Ex. 1 at 66; see also ECF No. 14 at 2 (Respondent's informal assessment raising this issue), ECF No. 18 (my Order to Show Cause discussing this issue and directing Petitioner to Show Cause why his brachial neuritis Table claim should not therefore be dismissed). Petitioner has offered no evidence or argument to the contrary, and has consented to the dismissal of this aspect of his overall case. ECF No. 19.

In regard to Petitioner's alternative claim of a Table SIRVA, Petitioner has likewise failed to establish the QAI requirements for a SIRVA Table case,⁴ given his treaters' assessments of "radicular pain in left arm" (Ex. 1 at 69) and "Parsonage-Turner syndrome" (Ex. 3 at 25), as well as Petitioner's pre-vaccination history of a left shoulder arthroplasty in January 2015 to treat osteoarthritis (ECF No. 13 at ¶2). See also ECF No.

On 9/6/17, the patient was in the ED for right eye pain and received a tetanus shot. Six hours later, he states that pain to the left arm began starting in the shoulder and radiating to the hand. Aleve and ibuprofen taken at home have been ineffective for pain relief. Hardware in the left arm s/p previous shoulder surgery noted. Due to persistent pain, he has come to the ED for further evaluation.

Ex. 1 at 66. The impression was radicular left arm pain. *Id.* at 69. On November 22, 2017, a diagnosis of Parsonage-Turner Syndrome was confirmed. Ex. 3 at 25.

Shoulder Injury Related to Vaccine Administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10)(emphasis added).

⁴ In pertinent part, the QAI for the Table Injury of SIRVA states:

18 at 2-3 (my Order to Show discussing these issues and directing Petitioner to Show Cause why his Table SIRVA claim should not be dismissed). Again, Petitioner has offered no additional evidence or argument to the contrary, and has consented to the dismissal of his Table SIRVA claim. ECF No. 19.

Accordingly, for the above stated reasons I find⁵ that Petitioner has failed to demonstrate the Table requirements for brachial neuritis (42 C.F.R. § 100.3(a)(I)(B)) and SIRVA (42 C.F.R. § 100.3(c)(10)), and hereby dismiss Petitioner's Table brachial neuritis and SIRVA claims.

III. Scheduling Order

In light of the instant ruling, I will proceed with transferring Petitioner's case out of SPU and will randomly reassign the case to a special master to conduct further proceedings to establish whether Petitioner has demonstrated an off-Table case for some kind of injury.⁶

On October 18, 2021, Petitioner filed a Status Report indicating that he was waiting to receive a set of records requested by Respondent from Hospital of Special Surgery and would file these records upon receipt. ECF No. 22. These records have not yet been filed. Accordingly, **Petitioner shall file his outstanding records from Hospital of Special Surgery, by no later than <u>February 10, 2022</u>.**

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master

⁵ I make these findings after a complete review of the record, including all medical records, affidavits, and all other additional evidence and filings from the parties.

⁶ I reject Respondent's assertion that a petitioner could *never* pursue an off-Table case of SIRVA, since it is envisionable that expert support could in a proper case help establish a comparable injury even if the literal Table requirements are not met (just as claimants can prove the flu vaccine caused GBS in a non-Table context). But I decline to make any preliminary findings in regard to whether the Petitioner *in this case* can establish entitlement to any off-Table injury.